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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,395	12/02/2004	Tokumi Ishikawa	2004 1847A	5078
513 7590 03/03/2010 WENDEROTH, LIND & PONACK, L.L.P. 1030 15th Street, N.W., Suite 400 East Washington, DC 20005-1503				
EXAMINER MATNEY, BROOKE MARIE				
ART UNIT 3763		PAPER NUMBER		
NOTIFICATION DATE 03/03/2010		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/516,395

Applicant(s)

ISHIKAWA ET AL.

Examiner

Brooke M. Matney

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 12-14 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SI/08)
Paper No(s)/Mail Date 9/23/2009, 1/26/2006, 11/28/2005, 3/4/2005
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. This office action is responsive to the Response to Election of Species Requirement filed on 12/23/2009. As directed by the response: Applicant elects Species I: Figs. 1, 2 and 4. Claims 1-11 and 15-19 read on the elected species. Thus, claims 1-11 and 15-19 are presently pending in the application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 2 recites the limitation "the driving means" in line 5. There is insufficient antecedent basis for this limitation in the claim. For the purposes of examination, Examiner will assume it should be "the first driving means".

5. Claim 5 recites the limitation "the body". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-11 and 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by *Lippe et al.* [U.S. Patent No. 6,171,276 B1].

As to claim 1, *Lippe et al.* discloses an automatic administration instrument for medical use for injecting a drug solution filled in a syringe, wherein a switching means (switch 11, Fig. 1A) provided on the body of the administration instrument is operated by pressing a part (cover 8) of the exterior of the body against a body region of a patient to which the drug solution is to be administered, thereby operating a first driving means (housing 2 and container 3 pushing needle 4 into a patient, Col. 11, ll. 59-66, Col. 16, ll. 11-15) so that an injection needle housed in the body protrudes from the body to perform needle insertion into the body region Fig. 1C) , and thereafter, a second driving means (motor 7) for driving the syringe is operated to administer the drug solution. The activation of the switching means results in the operation of the first driving means, driving the needle into the patient.

As to claim 2, *Lippe et al.* discloses an automatic administration instrument for medical use as defined in Claim 1 wherein, after a detection means (cover structure 10) detects that the administration instrument body is removed from the body region, the driving means is operated so that the injection needle that protrudes from the body to be inserted in the body region is housed in the administration instrument body (Col. 16, ll. 5-8). *Lippe et al.* teaches that the cover can be biased with a spring, so when the body is removed from the

region the detection means will no longer complete the circuit and the injection needle will be retracted into the housing.

As to claim 3, *Lippe et al.* discloses wherein a speed of inserting the injection needle or a speed of pulling out the injection needle is variable. The speed of insertion or retraction depends on how much resistance the user applies to the instrument in either direction.

As to claim 4, *Lippe et al.* discloses wherein a speed at which the drug solution is administered by the second driving means is variable (Col. 11, l. 66-Col. 12, l. 7). *Lippe et al.* teaches different delivery modes of operation that could deliver at different speeds.

As to claim 5, *Lippe et al.* discloses an automatic administration instrument for medical use for injecting a drug solution, said administration instrument being provided with an inner case (cover 8) that is slidably provided in an outer case (housing 2) of the body, an injection needle (4) that is attached to the inner case (via container 3), a syringe (syringe type container 3) that is replaceably attached to the inner case (Fig. 1A) and is filled with a drug solution, a first driving means for sliding (housing 2 and container 3 pushing needle 4 into a patient, Col. 11, ll. 59-66, Col. 16, ll. 11-15) the inner case in the outer case, a second driving means (motor 7) that is coupled to the syringe to administer the drug solution filled in the syringe, and a switch means (switch 11) for driving the first and second driving means; wherein, when performing insertion of the injection needle, the first driving means is operated by the switch means to slide

the inner case so that the injection needle protrudes from the outer case (Col. 16, ll. 1-5), thereby automatically inserting the needle into a body region of a patient to which the drug solution is to be administered.

As to claim 6, *Lippe et al.* discloses wherein, when performing removal of the injection needle, the inner case is slid so that the injection needle protruding from the outer case is housed in the outer case, thereby automatically removing the injection needle (Col. 16, ll. 5-8). *Lippe et al.* teaches that the cover can be biased with a spring, so when the inner case is slid away from the patient the injection needle is removed and housing in the outer case.

As to claim 7, *Lippe et al.* discloses further including a detection switch (cover switch 10) for detecting as to whether the administration instrument body contacts the body region to which the drug solution is to be administered (Col. 16, l. 8-29).

As to claim 8, *Lippe et al.* discloses wherein insertion of the injection needle is enabled when the detection switch detects that the administration instrument contacts the body region to which the drug solution is to be administered (Fig. 1C, Col. 16, ll. 12-16).

As to claim 9, *Lippe et al.* discloses wherein administration of the drug solution is stopped when the detection switch detects that the administration instrument does not contact the body region to which the drug solution is to be administered, during administration of the drug solution (Col. 16, ll. 8-12). When

the detection switch detects that the administration instrument is not in contact with the body region, the circuit is broken and the motor is stopped.

As to claim 10, *Lippe et al.* discloses wherein the operation of housing the injection needle into the body is carried out when the detection switch detects that the administration instrument does not contact the body region to which the drug solution is to be administered, during insertion of the injection needle (Col. 16, ll. 5-8). When the administration instrument does not contact the body region, the detection switch moves with the cover and the injection needle moves away from the body so that it is no longer in contact with the body region and is protected by the cover.

As to claims 11, 18 and 19, *Lippe et al.* discloses wherein the detection switch also serves as a switch for driving the first and second driving means. The detection switch must be engaged (10 must be aligned with 11) for the first and second driving means to operate.

As to claim 16, *Lippe et al.* discloses wherein a speed of inserting the injection needle or a speed of pulling out the injection needle is variable. The speed of insertion or retraction depends on how much resistance the user applies to the instrument in either direction.

As to claim 17, *Lippe et al.* discloses wherein a speed at which the drug solution is administered by the second driving means is variable (Col. 11, l. 66-Col. 12, l. 7). *Lippe et al.* teaches different delivery modes of operation that could deliver at different speeds.

8. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by *Hogan* [U.S. Patent No. 6,406,460 B1].

As to claim 15, *Hogan* discloses an automatic administration instrument for medical use wherein injection of a drug solution is not carried out when an injection needle is not attached to the body of the administration instrument (Fig. 1).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brooke M. Matney whose telephone number is (571)270-1457. The examiner can normally be reached on Monday-Thursday 9AM-7PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571)272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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